UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,491	07/31/2001	Shoulian Dong	3417	1435

22886 7590 04/29/2002

AFFYMETRIX, INC
ATTN: CHIEF IP COUNSEL, LEGAL DEPT.
3380 CENTRAL EXPRESSWAY
SANTA CLARA, CA 95051

EXAMINER	
GUNTER, DAVID R	
ART UNIT	PAPER NUMBER
1634	4

DATE MAILED: 04/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/920,491	DONG, SHOULIAN	
	Examiner	Art Unit	
	David R. Gunter	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Restriction

Restriction to one of the following is required under 35 U.S.C. 121:

I. Claims 1-19, drawn to a method of reducing the complexity of a nucleic acid sample, classified in class 435, subclass 6, encompass a distinct invention defined by the steps required to carry out the method (mode of operation), the function of the method, and the materials produced by the method (effects).

II. Claims 20-24, drawn to a method of analyzing a nucleic acid sample, classified in class 435, subclass 6, encompass a distinct invention defined by the steps required to carry out the method (mode of operation), the function of the method, and the materials produced by the method (effects).

III. Claims 25-28, drawn to a method of screening DNA sequence variations in an individual, classified in class 435, subclass 6, encompass a distinct invention defined by the steps required to carry out the method (mode of operation), the function of the method, and the materials produced by the method (effects).

IV. Claims 29-32, drawn to a method of screening for DNA sequence variation in a population of individuals, classified in class 435, subclass 6, encompass a distinct invention

defined by the steps required to carry out the method (mode of operation), the function of the method, and the materials produced by the method (effects).

V. Claim 33, drawn to a method of genotyping an individual, classified in class 435, subclass 6, encompasses a distinct invention defined by the steps required to carry out the method (mode of operation), the function of the method, and the materials produced by the method (effects).

VI. Claim 34, drawn to a kit for reducing the complexity of a nucleic acid sample, classified in class 435, subclass 6 encompasses a distinct invention.

Claims I-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions all vary in the steps required to carry out the method (mode of operation), the function of the method, and the materials produced by the method (effects).

Invention I describes a method for reducing the complexity of a nucleic acid sample by fragmenting the nucleic acid with a pair of restriction enzymes, ligating adapters to the ends of the fragments generated, and then selectively amplifying the fragments that were cut on one end by the first restriction enzyme and on the other end by the second restriction enzyme. The objective of the method is to reduce large nucleic acid molecules such as genomic DNA into

fragments of a size that are more readily manipulated, and to do so in a controlled and repeatable manner.

Invention II describes a method for analyzing a nucleic acid sample. In addition to the steps listed for invention I, invention II also includes the additional steps (modes of operation) of hybridizing the amplified fragments to a nucleic acid array and analyzing the resulting hybridization pattern. The effect of this invention is both to reduce the complexity of the nucleic acid as described in invention I and to provide information about the sequence of the fragments based on the pattern of hybridization to the nucleic acid array.

Invention III describes a method for screening for DNA sequence variations in an individual. Unlike invention II, invention III specifically states that the nucleic acid to be analyzed is DNA, and that a single individual will provide the DNA sample. This defines the mode of operation of invention II in such a way as to exclude RNA and to exclude pooled nucleic acid samples derived from a plurality of individuals. This defined mode of operation results in a corresponding reduction in the types of data (effects) that the method can provide.

Invention IV describes a method for screening for DNA sequence variation in a population of individuals. Invention IV differs from invention II by specifying both that the nucleic acid to by analyzed is DNA, and that the DNA will be provided by each member of a population. This defines the mode of operation of invention II in such as way as to exclude RNA and to exclude nucleic acid samples derived from a single individual. This defined mode of operation results in a corresponding reduction in the types of data (effects) that the method can provide. Invention IV differs from invention III by using DNA samples from a plurality of individuals and using a plurality of identical nucleic acid arrays. The effect of invention IV is

unique among inventions I-V in that it allows a measurement of the presence of absence of sequence variations across a population of individuals.

Invention V describes a method of genotyping an individual includes the steps of invention III, but specifies that the nucleic acid array to be used is designed to determine the presence or absence of one or more alleles of a collection of SNPs. This defines the mode of operation of invention III in such a way as to exclude a broad range of genetic analysis including those intended to identify the presence of lengthy nucleic acid sequences carried by the individual or to detect foreign nucleic acids such as those belonging to a virus or other pathogen. This defined mode of operation results in a corresponding reduction in the types of data (effects) that the method can provide.

Inventions I-V and invention VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case inventions I-V each constitute distinct inventions as described above. Invention VI describes a kit containing buffers and enzymes for fragmenting nucleic acid, ligase, and adapters and primers designed for the selective amplification of the nucleic acid fragments generated by the kit. These steps of digestion, ligation, and amplification are shared by inventions I-V. Therefore the product (the kit) as claimed can be used for five materially different processes as described by inventions I-V.

Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David R. Gunter whose telephone number is (703) 308-1701. The examiner can normally be reached on 9:00 - 5:00 M - F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

David R. Gunter, DVM, PhD
April 23, 2002